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NOTICE OF ALLOWANCE AND FEE(S) DUE

7590 06/28/2002

Attention of J Scot Wickhem  
Merchant & Gould PC  
P O Box 2903  
Minneapolis, MN 55402-0903

EXAMINER	
NATNITHITHADHA, NAVIN	
ART UNIT	CLASS-SUBCLASS
3736	600-345000

DATE MAILED: 06/28/2002

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,604	07/10/2000	James Say	12008.20USC1	1097

TITLE OF INVENTION: ELECTROCHEMICAL ANALYTE SENSOR

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1280	\$0	\$1280	09/30/2002

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. **PROSECUTION ON THE MERITS IS CLOSED.** THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. **THIS STATUTORY PERIOD CANNOT BE EXTENDED.** SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above. If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

B. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

☐ Applicant claims SMALL ENTITY status.  
See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER:** Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

# **PART B - FEE(S) TRANSMITTAL**

**Complete and send this form, together with applicable fee(s), to: Mail Box ISSUE FEE  
Commissioner for Patents  
Washington, D.C. 20231  
Fax (703)746-4000**

**INSTRUCTIONS:** This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

**CURRENT CORRESPONDENCE ADDRESS** (Note: Legibly mark-up with any corrections or use Block 1)

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Merchant & Gould PC  
P O Box 2903  
Minneapolis, MN 55402-0903

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

## **Certificate of Mailing or Transmission**

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above, or being facsimile transmitted to the USPTO, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

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nonprovisional	NO	\$1280	\$0	\$1280	09/30/2002
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EXAMINER	ART UNIT	CLASS-SUBCLASS
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NATNITHADHA, NAVIN	3736	600-345000
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1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 \_\_\_\_\_  
2 \_\_\_\_\_  
3 \_\_\_\_\_

## **3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)**

**PLEASE NOTE:** Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent)

☐ individual ☐ corporation or other private group entity ☐ government

4a. The following fee(s) are enclosed:

4b. Payment of Fee(s):

☐ Issue Fee

☐ A check in the amount of the fee(s) is enclosed.

☐ Publication Fee

☐ Payment by credit card. Form PTO-2038 is attached.

☐ Advance Order - # of Copies \_\_\_\_\_

☐ The Commissioner is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

Commissioner for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

(Authorized Signature)

(Date)

**NOTE:** The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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**TRANSMIT THIS FORM WITH FEE(S)**



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EXAMINER
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NATNITHITHADHA, NAVIN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 06/28/2002

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The patent term adjustment to date is 41 days. If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the term adjustment will be 41 days.

If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system. (<http://pair.uspto.gov>)

# Notice of Allowability

Application No.

09/613,604

Examiner

Navin Natnithithadha

Applicant(s)

SAY ET AL.

Art Unit

3736

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to May 21, 2002.
2. ☒ The allowed claim(s) is/are 127-135, 139-162 and 165-169.
3. ☒ The drawings filed on 10 July 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

- |  |  |
|--|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)  | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 4 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____    |
| 5 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. <u>3</u> | 6 <input type="checkbox"/> Examiner's Amendment/Comment                    |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|  | 9 <input type="checkbox"/> Other   |

*Kevin A. Shaver*  
6/27/02  
KEVIN SHAVER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700

### **Part III DETAILED ACTION**

1. Claims 1-127 are presented for examination.

#### ***Response to Amendment***

2. Claims 1, 2, 10-15, 20-22, 33, 34, 36-38, 48, 54-58, 70, 74, 81, 97, and 122 are amended.
3. Claim 127 is added.
4. Claims 3, 59-64, 79, 80, 85-91, and 123-126 are canceled.

#### ***Drawings***

5. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

#### ***Specification***

6. The disclosure is objected to because of the following informalities:  
on page 10, line 19, PCT Patent Application Number is missing; and  
on page 16, line 22, U.S. Application Serial Number is missing.  
Appropriate correction is required when the information becomes available.

7. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

*Claim Rejections - 35 USC § 102*

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 104, 105, 107, 108, and 118-120 are rejected under 35 U.S.C. 102(b) as being anticipated by Guilbeau et al, US 4,935,345.

Guilbeau et al teaches the invention (claims 104, 105, 107, and 108) as claimed, including an electrochemical sensor (e.g., see Abstract), comprising:

a substrate 10; and conductive material disposed on a surface of the substrate 10 to form a plurality of traces 12-20 (e.g., see col. 6, line 39 to col. 7, line 24 and see Fig. 1); wherein the plurality of conductive traces are separated on the surface of the substrate by 0.25 inches or less (e.g., see col. 7, line 50-66 and see col. 11, line 47-59).

Guilbeau et al teaches the invention (claim 118-120) as claimed, including method of determining a level of an analyte in a human (e.g., see Abstract), comprising:

generating a signal at thin film thermopile in response to the analyte; analyzing the signal to determine a level of the analyte; and producing a voltage between two conductive traces (e.g., see col. 4, line 29 to col. 5, line 19).

10. Claims 81 and 83 are rejected under 35 U.S.C. 102(b) as being anticipated by Hill et al, US 5,509,410.

Hill et al teaches the invention (claims 81 and 83) as claimed, including an electrochemical sensor for determining a level of an analyte in a fluid, comprising:

a substrate; a conductive material disposed on the substrate and forming a working electrode; and a catalyst disposed proximally to the working electrode to catalyze a reaction of the analyte resulting in a change in a level of a second compound; wherein the electrochemical sensor is responsive to the level of the second compound in the fluid (e.g., see col. 1, line 53 to col. 2, line 34).

### *Claim Rejections - 35 USC § 103*

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 103, 10-13, 20, 21, 54, and 74-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al, US 5,509,410, in view of Guilbeau et al, US 4,935,345.

Hill et al teaches the invention (claim 103) substantially as claimed, including a sensor system, comprising:

a substrate; a conductive material disposed on the substrate to form a working electrode, the conductive material comprising carbon; and an enzyme disposed proximate to the working electrode (e.g., see col. 2, lines 26-35, and see col. 12, lines 33-46).

Hill et al does not teach a subcutaneous implantable sensor. He teaches using drop of blood placed onto the sensing electrode (e.g., see col. 2, lines 26-34). However, Guilbeau et al teaches a implantable biochemical sensor comprising a substrate, a conductive material, and an enzyme (e.g., see Abstract, see Fig. 5, and see col. 12, line 60 to col. 13, line 15). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Hill et al with the teachings of Guilbeau et al to accurately measure, within the body of a human, the concentration of particular chemicals within body fluids.

As to claims 10 and 11, Hill et al teaches the electrochemical sensor configured for in vitro operation (e.g., see col. 2, lines 26-34) and Guilbeau et al teaches the electrochemical sensor for in vivo operation (e.g., see Abstract).

As to claims 12 and 13, Guilbeau et al teaches a substrate made of glass, silicon, ceramic, or plastic (e.g., see col. 2, lines 26-38) and Hill et al teaches a substrate made of epoxy glass (e.g., see col. 8, lines 12-24).



As to claim 20, Guilbeau et al teaches the conductive material comprises of metal (e.g., see col. 6, lines 26-57).

As to claim 21, Hill et al teaches the conductive material comprises carbon (e.g., see col. 12, lines 33-46).

As to claim 54, Guilbeau teach the analyte as glucose (e.g., see Abstract).

As to claim 74, both Hill et al and Guilbeau et al teaches a method of determining a level of an analyte in a fluid, the method comprising: contacting the fluid with the electrochemical sensor; generating an electrical signal in the sensor in response to the presence of the analyte; and determining a level of the analyte from the electrical signal (e.g., see Abstracts).

As to claim 75-78, Hill et al teaches the electrochemical sensor configured for in vitro operation (e.g., see col. 2, lines 26-34) and Guilbeau et al teaches the electrochemical sensor for in vivo operation (e.g., see Abstract).

13. Claims 92-94, 22, 23, 26-30, 100, and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al, US 5,509,410.

Hill et al teaches the invention (claim 92) as claimed, including an electrochemical sensor, comprising:

a substrate; and a working electrode disposed on the substrate, the working electrode comprising a carbon material (e.g., see col. 4, lines 16-40).

As to claim 92-94, Hill et al does not disclose the width of the working electrode. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Hill et al because it is a matter of engineering choice based on design parameters.

As to claims 22, 23, 26-30, Hill et al teaches using an active electrode, positioned to contact the liquid mixture and the first conductor, comprises a deposit of an enzyme capable of catalyzing a reaction (e.g., see col. 1, line 53 to col. 2, line 14). The enzyme is glucose oxidase or glucose dehydrogenase.

As to claims 100 and 101, Hill et al teaches the active electrode formed by printing an ink comprising a conductive compound (e.g., see col. 2, lines 1-14).

14. Claims 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guilbeau et al, US 4,935,345, in view of Hill et al, US 5,509,410.

Guilbeau et al teaches the invention (claim 109) as claimed including an electrochemical sensor, comprising:

a substrate 10, conductive material disposed on the substrate to form a working electrode 12; and a contact pad 13 disposed on the substrate 10 and connected to the working electrode 12 (e.g., see Figs. 1A-1D).

Guilbeau et al does not teach the contact pad made of non-metallic conductive material. However, Hill et al teaches a electrochemical sensor using an electrode made of a conductive

material such as carbon (e.g., see col. 4, lines 30-40). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Hill et al with the teachings of Guilbeau et al to accurately measure, within the body of a human, the concentration of particular chemicals within body fluids.

*Allowable Subject Matter*

15. Claims 35-38, 70, 71, 112-117, 122, and 127 are allowed.
16. Claims 1, 2, 4-9, 14-19, 24, 25, 31-34, 39-53, 55-58, 65-69, 72, 73, 82, 84, 95-99, 102, 106, 110, 111, and 121 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Conclusion*

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5,820,551 and US 5,727,548 are related U.S. Patents to US 5,509,410 which was used in the rejections above.

US 5,954,685 teaches an electrode assembly for use in a transdermal analyte sensor.

US 5,71,861 teaches a electrochemical sensor system for measuring analyte concentrations in a sample fluid.

US 5,400,782 teaches an electrode for monitoring and diagnostic applications which includes a fusible conductive substrate to which are fused the other components, such as the conductor, of the electrode.

US 5,322,063 teaches a biosensor for amperometric measurements wherein the measuring electrode is made of an electrically conductive carrier made of carbon.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emr. Navin Natnithithadha, whose telephone number is (703) 305-2445.

The examiner can normally be reached on M-TH from 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by phone fail, the examiner's supervisor, Cary E. O'Connor, can be reached at (703) 308-2701. Additionally, the fax phone for Art Unit 3736 is (703) 308-0758.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at (703) 308-1148.

Navin Natnithithadha  
Patent Examiner  
Art Unit 3736  
December 13, 2001